IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF WISCONSIN

NOVOZYMES A/S and NOVOZYMES NORTH AMERICA, INC.,

Plaintiffs,

v.

DANISCO A/S, GENENCOR INTERNATIONAL WISCONSIN, INC., DANISCO US INC., and DANISCO USA INC.,

Defendants.

Case No. 10-CV-251

Judge Barbara C. Crabb

NOVOZYMES' AMENDED PROPOSED JURY INSTRUCTIONS RE LIABILITY INSTRUCTIONS

In light of the Court's decision at the Pretrial Conference to break the liability phase of the trial into two parts, plaintiffs Novozymes A/S and Novozymes North America, Inc. (collectively, "Novozymes") hereby submit Novozymes' Amended Proposed Jury Instructions for instructions to be given during the two parts of the liability phase. Novozymes reserves the right to amend or supplement its Proposed Jury Instructions based upon further rulings of the Court or in response to any new instructions proposed by Defendants Danisco A/S, Genencor International Wisconsin, Inc., Danisco US Inc., and Danisco USA Inc. (collectively, "Danisco") and based upon the evidence actually admitted at trial.

¹ For the reasons explained in Novozymes' Motion *in Limine* No. 1 and during the Pretrial Conference, the issue of derivation should not be presented to the jury for decision at all and should certainly not be presented to the jury for decision if the jury finds that the specification of the '723 patent satisfies the written description requirement.

IV. <u>LIABILITY INSTRUCTIONS — PART I</u>

NOVOZYMES' PROPOSED INSTRUCTION 4.1

Summary of Contentions

I will first give you a summary of each side's contentions in this case. I will then tell you what each side must prove to win on each of its contentions.

As I previously told you, Novozymes [patent holder] contends that Danisco infringes [seeks money damages from alleged infringer for allegedly infringing] the '723 patent by making, importing, using, selling and offering for sale products that Novozymes [patent holder] argues are covered by claims 1-5, 8-13 and 15-16 of the patent. These are the asserted claims of the '723 patent. [[Patent holder] also argues that [alleged infringer] has [actively induced infringement of these claims of the [] patent by others] [contributed to the infringement of these claims of the [] patent by others].] The Court has already decided that certain questions of infringement have been decided in Novozymes' favor and are no longer in dispute. You, the jury, are to decide whether any of the asserted claims of the '723 patent are infringed by Danisco's "whole broth" products: Spezyme Alpha WB, ClearFlow WB, and GC133. To determine whether Danisco's whole broth products infringe the asserted claims of the '723 patent, you must only decide whether these products contain "an isolated variant of a parent alpha-amylase". I will explain in a moment how the Court has defined the term "isolated variant". The Court has already determined that the Spezyme Alpha WB, ClearFlow WB, and GC133 whole broth products satisfy the other requirements of claims 1–5, 8–13 and 15–16 of the '723 patent.

[The products that are alleged to infringe are [list of accused products or methods].]

<u>Danisco</u> [Alleged infringer] denies that <u>its whole broth products infringe</u> [has infringed] the asserted claims of the <u>'723</u> patent and argues that, in addition, <u>the asserted</u> claims are invalid.

Your job is to decide whether <u>Danisco's whole broth products infringe</u> the asserted claims of the <u>'723</u> patent [have been infringed] and whether any of the asserted claims of the <u>'723</u> patent are invalid.

[If you decide that any claim of the patent has been infringed and is not invalid, you will then need to decide any money damages to be awarded to [patent holder] to compensate it for the infringement. You will also need to make a finding as to whether the infringement was willful. If you decide that any infringement was willful, that decision should not affect any damage award you make. I will take willfulness into account later.]

Authorities:

Model Patent Jury Instructions for the Northern District of California § B.1; 35 U.S.C. § 271; Opinion and Order dated July 7, 2011 (Dkt. No. 399), at 38–39.

Interpretation of the Patent Claims²

[I [have provided you; will provide you] with a copy of Plaintiff's patent.] I have previously defined certain phrases in [some of] the claims of Novozymes' patent. You must use these definitions in making your decision. The phrases I have defined are as follows:

- "Increased thermostability" means that "a variant alpha-amylase consistently has
 greater residual alpha-amylase activity than the parent alpha-amylase at any time
 point at which at least one of the variant or parent alpha-amylase has residual
 activity".
- 2. "Isolated variant" means a variant alpha-amylase that has undergone a detectable amount of separation from cellular and/or non-cellular material and that has been separated to the extent necessary to perform its intended function in industrial applications. Complete separation from such material is not required. The variant also need not constitute a majority of the material in the accused product, nor represent any particular percentage of the material in the accused product, in order to be isolated.³
- 3. <u>A "Bacillus stearothermophilus</u> alpha-amylase" means an alpha-amylase "produced from an alpha-amylase gene of a *Bacillus stearothermophilus* organism."

² Novozymes cites these constructions as those adopted by the Court in its July 7, 2011 Order and subsequent orders and reserves the right to appellate review of the same. *See O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1359 (Fed. Cir. 2008).

³ Proposed by Novozymes. Dkt. No. 681, Novozymes' Memorandum in Support of the Construction of "Isolated Variant."

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Authorities:

Federal Civil Jury Instructions of the Seventh Circuit, Instruction No. 11.2.9; Opinion and Order dated July 7, 2011 (Dkt. No. 399), at 5–30; Order dated Aug. 24, 2011, at 2 (noting that the Court had previously construed "isolated" to mean "separated"); *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 384–91 (1996); *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1304 (Fed. Cir. 1999); *Cybor Corp. v. FAS Techs.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc).

Independent and Dependent Claims

Patent claims may exist in two forms, called independent claims and dependent claims.

An independent claim stands on its own and does not refer to any other claim of the patent. A dependent claim refers to at least one other claim in the patent. A dependent claim includes each of the requirements of the other claim[s] to which it refers, as well as the requirements in the dependent claim itself.

[Earlier I described] <u>Imagine</u> a hypothetical patent claim for a table that [described the] <u>has a</u> tabletop, four legs, and glue to hold the legs and tabletop together. That is an example of an independent claim. In that same hypothetical patent, a dependent claim might be one that stated, "the same table in the initial claim, where the tabletop is square."

Claims 1, 9 and 16 of the '723 patent are independent claims. Claims 2–8 of the '723 patent are dependent claims that depend from claim 1. Claims 10–15 of the '723 patent are dependent claims that depend from 9. Claim 17 of the '723 patent is a dependent claim that depends from claim 16.⁴

Authorities:

Federal Civil Jury Instructions of the Seventh Circuit, Instruction No. 11.2.6; 35 U.S.C. § 112, ¶¶ 3–4; *Glaxo Group Ltd. v. Ranbaxy Pharms., Inc.*, 262 F. 3d 1333, 1336 (Fed. Cir. 2001); *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006).

⁴ Novozymes contends that Danisco is not entitled to ask the jury for a finding of invalidity on unasserted claims 6–7, 14 and 17.

Infringement

Novozymes [Plaintiff] contends that <u>Danisco</u> [Defendant] has infringed claims <u>1–5, 8–13</u> and <u>15–16</u> of the '723 [Plaintiff's] patent. To succeed on this contention, <u>Novozymes</u> [Plaintiff] must prove [the following] by a preponderance of the evidence[:] that <u>Danisco's accused "whole broth"</u> alpha-amylase products infringe the asserted claims of the patent.

- [1. Every requirement in [the particular claim of Plaintiff's patent that you are considering; Plaintiff's patent] is found in Defendant's [product; process]; and
- 2. Defendant [made, used, sold, offered for sale, or imported] that [product; process] [in; into] the United States.]

As I have explained, Danisco's whole broth products are Spezyme Alpha WB, ClearFlow WB, and GC133. For each of the Danisco whole broth products, the only question remaining with respect to infringement is whether that product satisfies the "isolated variant" requirement in claims 1–5, 8–13 and 15–16 of the '723 patent. The Court has already found that the whole broth products satisfy all other requirements in claims 1–5, 8–13 and 15–16 of the '723 patent.

Consequently, if you, the jury, find that each of the whole broth products contains an "isolated variant", then you must also find that those products infringe claims 1–5, 8–13 and 15–16 of the '723 patent.

Authorities:

Federal Civil Jury Instructions of the Seventh Circuit, Instruction No. 11.2.10 (modified to add specifics of this case); Opinion and Order dated July 7, 2011 (Dkt. No. 399), at 4–30, 38–39; Order dated Aug. 24, 2011 (Dkt. No. 453); *Riles v. Shell Exploration & Prod. Co.*, 298 F.3d 1302, 1308 (Fed. Cir. 2002); *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1376 (Fed. Cir. 2005); *PSC Computer Prods., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1357 (Fed. Cir. 2004); *Cross Med. Prods.v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1310 (Fed. Cir. 2005).

Infringement — **Special Instruction**

Withdrawn given the Court's Order granting Novozymes' Motion in Limine No. 2 with respect to the first part of the liability phase of the trial.

Validity — General

<u>Danisco</u> [Defendant] has challenged the validity of the '723 patent claims on the grounds that the '723 patent does not contain an adequate written description of the claimed invention and that the '723 patent is not enabled.

Each of the claims of the <u>'723</u> patent is presumed to be valid. For that reason, <u>the law requires that Danisco</u> [Defendant] prove [has the burden of proving] invalidity by clear and convincing evidence. "Clear and convincing" evidence means evidence that convinces you that it is highly probable that the particular proposition is true. [You also may have heard of a burden of proof used in criminal cases called "beyond a reasonable doubt," which is a higher burden of proof than "clear and convincing" evidence. You must not apply the criminal standard in this case.]

You must evaluate and determine separately the validity of each claim of the '723 patent.⁵

Authorities:

Federal Civil Jury Instructions of the Seventh Circuit, Instruction No. 11.3.1 (modified to add specifics of this case); 35 U.S.C. § 282; *Microsoft Corp. v. i4i Ltd.*, 131 S.Ct. 2238 (2011) (holding that an invalidity defense must be proved by clear and convincing evidence); *Avia Group Int'l, Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1562 (Fed. Cir. 1988); *DMI, Inc. v. Deere & Co.*, 802 F.2d 421, 427 (Fed. Cir. 1986); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983).

⁵ Novozymes contends that Danisco is not entitled to ask the jury for a finding of invalidity on unasserted claims 6–7, 14 and 17.

Written Description Requirement

The law requires that Danisco [alleged infringer] [can meet its burden of proving that a patent claim is invalid by showing] prove by clear and convincing evidence that the patent does not contain an adequate written description of the claimed invention. The purpose of this written description requirement is to make sure that a patent describes the technology it seeks to claim as an invention and to demonstrate that the inventor was in possession of the invention at the time the application for the patent was filed, even though the claims may have been changed or new claims added since that time.

The written description requirement is satisfied if a person of ordinary skill in the <u>art</u> [field] reading the patent application as originally filed would recognize that the patent application described the invention as claimed, even though the description may not use the exact words found in the claim. A requirement in a claim need not be specifically disclosed in the patent application as originally filed if a person of ordinary skill would understand that the missing requirement is necessarily implied in the patent application as originally filed.

Whether a patent specification satisfies the written description requirement is evaluated from the perspective of one of ordinary skill in the art as of the filing date of Novozymes' November 16, 2000 application.

The level of detail required to satisfy the written description requirement varies

depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.

The written description requirement does not require that the specification contain examples of the invention, nor does it require that the inventors have actually made an example

of the invention. However, a mere wish or plan for obtaining the claimed invention is not adequate written description.

Authorities:

Model Patent Jury Instructions for the Northern District of California, Instruction No. 4.2a; Federal Civil Jury Instructions of the Seventh Circuit, Instruction No. 11.3.2.1; 35 U.S.C. § 112; *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351–52 (Fed. Cir. 2010) (en banc) ("We have made clear that the written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement."); *Falkner v. Inglis*, 448 F.3d 1357, 1366–67 (Fed. Cir. 2006); *Capon v. Eshhar*, 418 F.3d 1349, 1356–58 (Fed. Cir. 2005); *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1348 (Fed. Cir. 2011).

Written Description Requirement — Special Instruction

The parties do not dispute that Danisco was selling its accused alpha-amylase products before Novozymes' '723 patent issued. The law permits Novozymes to obtain patent claims covering Danisco's accused alpha-amylase products after Novozymes discovered that Danisco was selling those products in the market, so long as those patent claims are supported by an adequate written description.

Authorities:

In re Bogese, 303 F.3d 1362, 1369 (Fed. Cir. 2002); Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 874 (Fed. Cir. 1988); Semiconductor Energy Lab. Co. v. Samsung Elecs. Co., 204 F.3d 1368, 1382-83 (Fed. Cir. 2000).

Enablement Requirement

The law requires that <u>Danisco</u> [Alleged infringer] [can meet its burden of proving that a patent claim is invalid by showing] <u>prove by clear and convincing evidence</u> that the patent does not contain a description of the claimed invention that is sufficiently full and clear to enable a person of ordinary skill in the <u>art</u> [field] to make and use the invention. This is known as the enablement requirement.

A patent need not teach, and preferably omits, what is well known in the art. A [The] patent may be enabling even though it does not expressly state some information if a person of ordinary skill in the art [field] could make and use the invention without undue [having to do excessive] experimentation. Even a considerable amount of experimentation is not undue so long as it is routine experimentation.

[In determining whether excessive experimentation is required, you may consider the following factors:

the scope of the claimed invention;

the amount of guidance presented in the patent;

the amount of experimentation necessary;

the time and cost of any necessary experimentation;

how routine any necessary experimentation is in the field of [identify field];

whether the patent discloses specific working examples of the claimed invention;

the nature and predictability of the field; and

the level of ordinary skill in the field of [identity field].]⁶

Whether a patent specification satisfies the enablement requirement is evaluated from the perspective of one of ordinary skill in the art [field] as of the filing date of Novozymes'

November 16, 2000 application.

[The question of whether a patent is enabling is judged as of the date the original application for the patent was first filed.]

Authorities:

Model Patent Jury Instructions for the Northern District of California (2007), Instruction No. 4.2b; Federal Civil Jury Instructions of the Seventh Circuit, Instruction No. 11.3.2.2; 35 U.S.C. § 112; AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1244 (Fed. Cir. 2003); Ajinomoto Co. v. Archer-Daniels-Midland Co., 228 F.3d 1338, 1345–46 (Fed. Cir. 2000); In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988); Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986); Falkner v. Inglis, 448 F.3d 1357, 1365 (Fed. Cir. 2006).

⁶ The Committee on Pattern Civil Jury Instructions of the Seventh Circuit counsels against including the *Wands* factors in an enablement instruction. Federal Civil Jury Instructions of the Seventh Circuit, Instruction No. 11.3.2.2, Committee Comment 3.

Derivation — **General**

Withdrawn and re-submitted as Instruction No. 7.1.

Derivation — Special Instruction

Withdrawn. For the reasons explained in Novozymes' Motion in Limine No. 1 and during the Pretrial Conference, the issue of derivation should not be presented to the jury for decision at all and should certainly not be presented to the jury for decision if the jury finds that the specification of the '723 patent satisfies the written description requirement.

Person of Ordinary Skill in the Art⁷

Several times in my instructions I have referred to a person of ordinary skill in the art.

[Some issues in patent cases are determined by reference to a "person of ordinary skill in the field of the invention," a term that I will use later in these instructions.] In this case, Novozymes contends the field of the invention is alpha-amylase enzymes. Danisco contends that the field of the invention is protein engineering.

The parties agree that a person of ordinary skill, determined as of 2000–2001, would typically have a Ph.D. degree in biochemistry, molecular biology, or a related area, with two to four years of work experience. The person of ordinary skill may alternatively have a Master of Science degree, but must then also possess at least four to eight years of relevant work experience.

In addition, the parties agree that the person of ordinary skill would have experience in recombinant DNA techniques, protein science, and protein engineering. Experience working with recombinant DNA includes an understanding of molecular biology techniques such as making random or specific site-directed alterations to a DNA sequence. Experience in protein science includes knowledge of how to express a DNA sequence in host cells, familiarity with techniques for purifying expressed proteins, and assessing the activity and stability of proteins. Experience in protein engineering includes comparison of protein sequences by sequence alignment techniques, downloading coordinates for protein structures, and viewing three-dimensional protein structures using computer-implemented methodologies.

It is up to you to decide the level of ordinary skill. In making this decision, you should consider all the evidence, including:

⁷ This amended version of Novozymes' Proposed Instruction 4.12 incorporates the agreement reached by the parties as to a person of ordinary skill in the art.

- the levels of education and experience of persons working in the field;
- the types of problems encountered in the field; and
- the sophistication of the technology in the field.

Authorities:

Federal Civil Jury Instructions of the Seventh Circuit, Instruction No. 11.2.2 (modified to add specifics of this case); *Graham v. John Deere Co.*, 383 U.S. 1 (1966); *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1125 (Fed. Cir. 2000); *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1355 (Fed. Cir. 2000); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718–19 (Fed. Cir. 1991).

No Requirement that Novozymes Make, Use, or Sell the Invention

The law does not require that Novozymes itself make, use, or sell the invention claimed in the '723 patent. The fact that Novozymes does not currently make, use, or sell the invention claimed in the '723 patent has no bearing on whether Danisco infringes the '723 patent or whether the '723 patent is valid.

Authorities:

Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1545–48 (Fed. Cir. 1995) (en banc); King Instruments Corp. v. Perego, 65 F.3d 941, 947–49 (Fed. Cir. 1995).

VII. <u>LIABILITY INSTRUCTIONS — PART II (DERIVATION)</u>

NOVOZYMES' PROPOSED INSTRUCTION 7.1

Derivation — General

To prove derivation, Danisco must prove a prior, complete conception of the invention claimed in the '723 patent and communication of that complete conception to Novozymes, before Novozymes conceived of the invention claimed in the '723 patent. The communication of the complete conception to Novozymes must be sufficient to enable a person of ordinary skill in the art to practice the claimed invention.⁸

Each of the claims of the <u>'723</u> patent is presumed to be valid. For that reason, <u>the law requires that Danisco</u> [Defendant] prove <u>derivation</u> [has the burden of proving invalidity] by clear and convincing evidence. "Clear and convincing" evidence means evidence that convinces you that it is highly probable that the particular proposition is true. [You also may have heard of a burden of proof used in criminal cases called "beyond a reasonable doubt," which is a higher burden of proof than "clear and convincing" evidence. You must not apply the criminal standard in this case.]

You must evaluate and determine separately the <u>issue of derivation for</u> [validity of] each claim of the '723 patent.⁹

Authorities:

35 U.S.C. § 102(f); Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573, 1576–78 (Fed. Cir. 1997); Price v. Symsek, 988 F.2d 1187, 1190 (Fed. Cir. 1993); Hegewick v. Akers, 497 F.2d 905, 908 (C.C.P.A. 1974).

⁸ The text following this footnote is based on Instruction No. 11.3.1 of the Federal Civil Jury Instructions of the Seventh Circuit. Supporting authorities for this section are the same as for Novozymes' Proposed Instruction No. 4.6.

⁹ Novozymes contends that Danisco is not entitled to ask the jury for a finding of invalidity on unasserted claims 6–7, 14 and 17.

Derivation — Special Instruction

The parties do not dispute that Danisco was selling its accused alpha-amylase products before Novozymes' '723 patent issued. The law permits Novozymes to obtain patent claims covering Danisco's accused alpha-amylase products after Novozymes discovered that Danisco was selling those products in the market, so long as Novozymes did not derive the claimed invention from Danisco.

Authorities:

In re Bogese, 303 F.3d 1362, 1369 (Fed. Cir. 2002); Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 874 (Fed. Cir. 1988); Semiconductor Energy Lab. Co. v. Samsung Elecs. Co., 204 F.3d 1368, 1382-83 (Fed. Cir. 2000).

No Requirement that Novozymes Make, Use, or Sell the Invention

The law does not require that Novozymes itself make, use, or sell the invention claimed in the '723 patent. The fact that Novozymes does not currently make, use, or sell the invention claimed in the '723 patent has no bearing on whether Novozymes derived the claimed invention from Danisco.

Authorities:

Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1545–48 (Fed. Cir. 1995) (en banc); King Instruments Corp. v. Perego, 65 F.3d 941, 947–49 (Fed. Cir. 1995); Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573, 1576–78 (Fed. Cir. 1997).

Dated: October 16, 2011 Respectfully submitted,

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